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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,069	01/03/2007	Sudeepta Aggarwal	GNE-0269 R1	5360

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Arnold & Porter LLP (24126)
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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

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03/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,069	AGGARWAL ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-45 and 47-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-45 and 47-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/30/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 6/30/09 have been fully considered but they are not persuasive.

Claims 1-40 and 45 have been cancelled. Claims 41-45 and 47-52 are under consideration by the examiner.

Drawings

The replacement drawings (400 pages) were received on 6/30/09. These drawings are accepted.

Specification

The substitute specification filed 6/30/09 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: The statement required by 37 CFR 1.125(b) concerning lack of new matter is missing. See also MPEP 608.01(q).

The specification remains objected to for reasons of record.

The specification is additionally deficient because the description portion of this application contains a computer program listing consisting of more than three hundred (300) lines. In accordance with 37 CFR 1.96(c), a computer program listing of more than three hundred lines must be submitted as a computer program listing appendix on compact disc conforming to the standards set forth in 37 CFR 1.96(c)(2) and must be appropriately referenced in the specification (see 37 CFR 1.77(b)(5)). Accordingly, applicant is required to cancel the computer program listing appearing in the specification as Table 1, file a computer program listing appendix on compact disc in compliance with 37 CFR 1.96(c) and insert an appropriate reference

to the newly added computer program listing appendix on compact disc at the beginning of the specification.

In addition, the type font and line spacing in the original specification filed 4/28/05 appears to be too small. See MPEP 608.01 regarding acceptable font sizes and line spacing.

Applicant is reminded that any new substitute specification should include a description of each figure subpart found in the replacement drawings filed 6/30/09 in the Brief Description of the Drawings.

35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-45 and 47-52 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

The specification discloses a nucleic acid molecule (SEQ ID NO:2385) encoding the polypeptide PRO85142 (SEQ ID NO:2386). The nucleic acid is contained in a clone designated as clone DNA329612. There is no disclosure of PRO85142 functional activity or pattern of expression in various tissues. There is no disclosure of proteins related to PRO85142 by either

functional or sequence identity. The activity of PRO85142 polypeptide and its physical function are unknown. Expression levels of a gene encoding SEQ ID NO: 2386 is not correlated to any immune related disease in a mammal or inflammatory immune response in a mammal (claims 41 and 43). Note that the specification discloses no **gene** encoding SEQ ID NO: 2386. SEQ ID NO: 2386 is a **cDNA**. Formation of a complex between a polypeptide comprising SEQ ID NO: 2386 and an antibody against SEQ ID NO: 2386 is not correlated to any immune related disease in a mammal (claim 42). Note that the specification discloses no antibodies specific to SEQ ID NO: 2386 and identifies no epitopes for this protein.

It would require further experimentation and independent inventive judgment to determine if the polypeptide of SEQ ID NO: 2386, genes encoding it, or antibodies to it could be used in the claimed methods. Thus, no substantial utility has been established for the claimed methods. Identifying and studying the properties of a nucleic acid to determine if it encodes a protein and then identifying and studying the properties of the protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. No "immediate benefit to the public" is provided based upon the information disclosed in the specification. In all cases, experimentation on the sequence itself is required to further characterize it in order to use it in the manner disclosed.

In *Brenner v. Manson*, 148 USPQ 689, 696 (US, 1966), the Court held that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing," and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." The original disclosure lacks any successful conclusion for even one of

the potential immune related diseases or inflammatory immune responses disclosed. Thus, no "substantial" or "real world" utility has been disclosed.

The limited information set forth in the specification with respect to SEQ ID NO: 2386 is insufficient to establish a specific, substantial, and credible utility for the claimed methods.

Claims 41-45 and 47-52 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Applicant's arguments are unpersuasive. The specification does **not** disclose that PRO85142 is significantly overexpressed in activated CD4+ T cells as compared to resting cells. Note that this is **not** one of the polypeptides mentioned in the last paragraph of Example 1 in the specification.

Applicant's arguments concerning Molloy et al. (2009) are unpersuasive. Molloy et al. (2009) was published well after the effective filing date of the instant application. There is nothing in Molloy et al. and no evidence of record that SEQ ID NO: 2386 corresponds to TLT2 as argued by applicant. Molloy et al. does not appear to discuss TLT2. Furthermore, Molloy et al. (2009) does not provide evidence that any protein (or antibody to said protein) or gene corresponding to SEQ ID NO: 2386 is diagnostic for any immune related diseases or any inflammatory immune responses embraced by the claims. It does not establish enablement for

the full scope of the claims. The originally filed specification does not appear to disclose TLT2 or the TREM family.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45 is confusing in reciting "5.times." in two places and "50.mu.g/ml." It appearts that this may be a word processing error.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa